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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,174	10/12/2000	Hilary Koprowski	JEFF-KOPO1.P	2234

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EXAMINER

CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/673,174	<b>Applicant(s)</b> KOPROWSKI ET AL.	
	<b>Examiner</b> Stacy B Chen	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 17-28 is/are pending in the application.  
     4a) Of the above claim(s) 17-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/04; 6/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. Applicant's response filed June 10, 2004 is acknowledged and entered. Claims 1-4 and 17-28 are pending. In the Office Action dated February 24, 2004, the Office indicated that newly added claims 17-28 were directed to an invention(s) that is independent or distinct from the invention originally claimed. Applicant argues that the Office improperly subjected the claims to U.S. restriction practice since the application is a national stage application. Applicant also correctly pointed out that a showing of burden related to searching is not required for determining lack of unity of invention. In response, the asserted special technical feature linking the claims together is the infection of a single host plant with several recombinant viral vectors. The vectors carry heterologous genes that, when expressed in the plant, combine to form a polypeptide. This feature is anticipated by the prior art, exemplified by the rejection of claims 1-4 under 35 U.S.C. 103(a), and is therefore not a special technical feature. The claims lack unity of invention. Further, the differences between the inventions are outlined below.

- Claims 1-4, drawn to a method of producing a full-length antibody in a host plant using two viral vectors. The first vector encodes a movement protein, coat protein, and a heavy chain of an antibody. The second vector encodes a movement protein, coat protein and a light chain of an antibody
- Claims 17-23, drawn to a method of producing a full-length antibody in a host plant using two viral vectors. The first vector encodes a movement protein and a foreign polypeptide. The second vector encodes a capsid protein and foreign polypeptide.

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- Claims 24-27, drawn to a method of producing a full-length antibody in a host plant using one viral vector. The vector encodes a movement protein, capsid protein and two foreign polypeptides.
- Claim 28, drawn to a method of producing a full-length antibody in a host plant using three viral vectors. The first vector encodes a movement protein and a capsid protein. The second vector encodes a movement protein and a heavy chain of an antibody. The third vector encodes a movement protein, capsid protein and a light chain of an antibody.

The number of vectors differs among several of the groups, as well as the *components* in the vectors. These methods require different components and associated method steps. Therefore, the restriction is deemed proper and made FINAL.

### ***Claim Rejections - 35 USC § 103***

2. Claims 1-4 remain rejected under 35 U.S.C. 103(a) as obvious over Donson *et al.* (5,316,931, herein “Donson”) in view of Ma *et al.* (*Eur. J. Immunol.* 24 :131-138, 1994, herein “Ma”) and Scholthof *et al.* (*Ann. Rev. Phytopathol.* 34:299-323, 1996, herein “Scholthof”), for reasons of record. Applicant’s arguments have been carefully considered with respect to the claims under examination. Applicant’s substantive arguments are primarily directed to the following:

- Donson does not show the actual “successful” production of antibodies using a viral vector. Donson speculates that antibodies can be produced by a viral vector in a plant.
  - In response, Donson is not required to provide a working example, only a reasonable expectation of success. Applicant has failed to present facts that

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would lead one of ordinary skill to doubt that an antibody could not be produced in a plant using a viral vector.

- Donson only teaches that a single viral vector can cause systemic infection in a plant.

One of ordinary skill would expect that multiple viral vectors would have to overcome the complex defenses of the plant.

- In response, one of ordinary skill would expect that plants are exposed to viruses as part of their normal life cycle. Complete avoidance of exposure to viruses or other potentially pathogenic or non-pathogenic organisms is not likely, even in the most controlled laboratory setting. Given that a plant is exposed to viruses naturally, Donson's application of one virus vector leads one to have a reasonable expectation of success. If Donson's plant, which has been exposed naturally to other viruses, can produce a polypeptide with a single viral vector, then a multi-vector system would be expected to produce a polypeptide. While there may be obstacles to overcoming the plant's defenses, it is possible to overcome them.

- Ma fails to disclose a viral vector approach and fails to suggest multiple viral vectors.

- In response, Ma is not relied upon for teaching viral vector technology. Ma is relied upon for teaching that separate pieces of the antibody (heavy and light chains) can be produced and associate upon expression.

- Scholthof fails to provide motivation to combine the teachings of Ma with Donson because Scholthof teaches that multiple recombinant viral vectors are not stable and may lose the gene of interest in recombination events. Further, Scholthof fails to suggest that there is an advantage in using multiple vectors versus a single vector.

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- In response, Scholthof does not preclude the use of multiple viral vectors, nor does Scholthof have to indicate that multiple vectors are preferable to single vectors. While the expectation of success may not be 100%, there remains a reasonable expectation of success. Scholthof teaches that multiple viral vectors can be used, which is what Applicant is claiming.

***Conclusion***

3. No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30).


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Stacy B. Chen  
July 28, 2004



JAMES HOUSEL 8/7/04  
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